

**CLAIMS:**

1. A percutaneous heart valve prosthesis comprising:  
a valve body having a valve body first end, a valve body second end and a  
passage extending along a longitudinal axis between said valve body first end and said  
5 valve body second end, said valve body being collapsible about said longitudinal axis for  
delivery via catheter;  
one or more flexible valve elements secured to said valve body and extending  
across said passage for blocking bloodflow in one direction through said passage;  
an anchor frame formed of elongate elastic anchor frame elements, said  
10 anchor frame being collapsible from a stable substantially flat disc-like configuration to  
an unstable elongate configuration for location within a catheter; and  
a flexible anchor line secured to and extending between said valve body and  
said anchor device.
2. The prosthesis of claim 1 wherein said anchor frame elements are each  
15 formed of a superelastic shape memory material.
3. The prosthesis of claim 1 wherein said valve body comprises a collapsible  
valve body frame formed of elongate elastic valve body elements.
4. The prosthesis of claim 3 wherein said valve body frame elements are each  
formed of a superelastic shape memory material.
- 20 5. The prosthesis of claim 1 wherein said valve body tapers toward said valve  
body first end.
6. The prosthesis of claim 5 wherein said anchor line is secured to said valve  
body first end.
7. The prosthesis of claim 3 wherein said valve body frame comprises at least  
25 three valve body sub-frame members, each said valve body sub-frame member having the  
general form of a deltoid, each said deltoid having acute-angled vertices at said valve  
body first and second ends, and oblique-angled vertices located between said valve body  
first and second ends.
8. The prosthesis of claim 7 wherein each said valve body sub-frame member  
30 has the general form of a rhombus.

9. The prosthesis of claim 7 wherein adjacent said valve body sub-frame members are joined at respective said oblique-angled vertices.

10. The prosthesis of claim 9 wherein each said sub-frame member further comprises a collapsible diagonal element extending between said oblique-angled vertices.

5 11. The prosthesis of claim 10 wherein said one or more valve elements is/are secured to said diagonal elements.

12. The prosthesis of claim 3 wherein said valve body frame is in the general form of a collapsible cylindrical ring.

10 13. The prosthesis of claim 1 wherein said prosthesis further comprises a plurality of prongs spaced about a periphery of said valve body for engaging the native wall of a valve orifice in use.

14. The prosthesis of claim 1 wherein said prosthesis further comprises a flexible skirt extending about a periphery of said valve body for blocking blood flow in said one direction between said valve body and the native wall of a valve orifice in use.

15 15. The prosthesis of claim 14 wherein said flexible skirt is formed of biological material.

16. The prosthesis of claim 15 wherein said flexible skirt is formed of pericardial material.

17. The prosthesis of claim 1 wherein said prosthesis is a mitral valve prosthesis.

20 18. A percutaneous heart valve replacement system comprising:

a catheter having a catheter first end and a catheter second end;

a prosthesis as defined in claim 1 located in said catheter, said valve body being in a collapsed state and located towards said catheter first end, said anchor device being in a collapsed state and located between said valve body and said catheter second end; and

25

an elongate guide element having a guide element first end and a guide element second end, said guide element first end being detachably attached to said anchor device and said guide element second end extending beyond said catheter second end.

19. A percutaneous heart valve prosthesis comprising:

30 a valve body having a valve body first end, a valve body second end and a passage extending along a longitudinal axis between said valve body first end and said valve body second end, said valve being collapsible about said longitudinal axis for delivery via catheter; and

one or more flexible valve elements secured to said valve body and extending across said passage for blocking bloodflow in one direction through said passage;

wherein said valve body tapers linearly from said valve body second end to said valve body first end, said valve body first end being sized to pass through a valve orifice associated with a heart valve to be replaced, said valve body second end being  
5 sized so as not to pass through the valve orifice.

20. The prosthesis of claim 19 wherein said valve body comprises a collapsible valve body frame formed of elongate elastic valve body elements.

21. The prosthesis of claim 20 wherein said valve body frame elements are each  
10 formed of a superelastic shape memory material.

22. The prosthesis of claim 20 wherein said valve body frame comprises at least three valve body sub-frame members, each said valve body sub-frame member having the general form of a deltoid, each said deltoid having acute-angled vertices at said valve body first and second ends, and oblique-angled vertices located between said valve body  
15 first and second ends.

23. The prosthesis of claim 22 wherein each said valve body sub-frame member has the general form of a rhombus.

24. The prosthesis of claim 22 wherein adjacent said valve body sub-frame members are joined at respective said oblique-angled vertices.

20 25. The prosthesis of claim 24 wherein each said sub-frame member further comprises a collapsible diagonal element extending between said oblique-angled vertices.

26. The prosthesis of claim 25 wherein said one or more valve elements is/are secured to said diagonal elements.

27. The prosthesis of claim 19 wherein said prosthesis is a mitral valve prosthesis.

25 28. The prosthesis of claim 19 wherein said prosthesis further comprises a plurality of prongs spaced around a periphery of said valve body second end.

29. A percutaneous heart valve replacement system comprising:

a catheter having a catheter first end and a catheter second end;

a prosthesis as defined in claim 19 located in said catheter, said valve body  
30 being in a collapsed state and located towards said catheter first end; and

an elongate guide element having a guide element first end and a guide element second end, said guide element first end being detachably attached to said prosthesis and said guide element second end extending beyond said catheter second end.

30. A percutaneous heart valve prosthesis comprising:

a valve body having a valve body first end, a valve body second end and a passage extending along a longitudinal axis between said valve body first end and said valve body second end, said valve being collapsible about said longitudinal axis for

5 delivery via catheter;

one or more flexible valve elements secured to said valve body and extending across said passage for blocking bloodflow in one direction through said passage; and

a plurality of prongs spaced about a periphery of said valve body second end;

wherein said valve body tapers toward said valve body first end, said valve  
10 body first end being sized to pass through a valve orifice associated with a heart valve to be replaced, said valve body second end being sized so as not to pass through the valve orifice.

31. The prosthesis of claim 30 wherein said valve body comprises a collapsible valve body frame formed of elongate elastic valve body elements.

15 32. The prosthesis of claim 31 wherein said valve body frame elements are each formed of a superelastic shape memory material.

33. The prosthesis of claim 31 wherein said valve body frame comprises at least three valve body sub-frame members, each said valve body sub-frame member having the general form of a deltoid, each said deltoid having acute-angled vertices at said valve  
20 body first and second ends, and oblique-angled vertices located between said valve body first and second ends.

34. The prosthesis of claim 33 wherein each said valve body sub-frame member has the general form of a rhombus.

25 35. The prosthesis of claim 33 wherein adjacent said valve body sub-frame members are joined at respective said oblique-angled vertices.

36. The prosthesis of claim 35 wherein each said sub-frame member further comprises a collapsible diagonal element extending between said oblique-angled vertices.

37. The prosthesis of claim 36 wherein said one or more valve elements is/are secured to said diagonal elements.

30 38. The prosthesis of claim 30 wherein said prosthesis is a mitral valve prosthesis.

39. A percutaneous heart valve replacement system comprising:

a catheter having a catheter first end and a catheter second end;

a prosthesis as defined in claim 30 located in said catheter, said valve body being in a collapsed state and located towards said catheter first end; and

an elongate guide element having a guide element first end and a guide element second end, said guide element first end being detachably attached to said prosthesis and said guide element second end extending beyond said catheter second end.

40. A percutaneous heart valve prosthesis comprising:

5 a valve body having a valve body first end, a valve body second end and a passage extending along a longitudinal axis between said valve body first end and said valve body second end, said valve body being collapsible about said longitudinal axis for delivery via catheter;

10 one or more flexible valve elements secured to said valve body and extending across said passage for blocking bloodflow in one direction through said passage; and  
a flexible skirt extending about a periphery of said valve body for blocking bloodflow in said one direction between said valve body and the native wall of a valve orifice in use.

15 41. The prosthesis of claim 40 wherein said flexible skirt is formed of biological material.

42. The prosthesis of claim 41 wherein said flexible skirt is formed of pericardial material.

43. The prosthesis of claim 40 wherein said prosthesis is a mitral valve prosthesis.

20 44. A percutaneous heart valve replacement system comprising:  
a catheter having a catheter first end and a catheter second end;  
a prosthesis as defined in claim 40 located in said catheter, said valve body being in a collapsed state and located towards said catheter first end; and

25 an elongate guide element having a guide element first end and a guide element second end, said guide element first end being detachably attached to said prosthesis and said guide element second end extending beyond said catheter second end.

45. A method of treating a failed or failing mitral valve comprising the steps of:  
advancing a first end of a catheter through the venous system of a patient to be treated into the right atrium of the patient's heart;

30 creating a puncture in the inter-atrial septum of the heart;  
advancing said catheter first end through said puncture, into the left atrium, through the native mitral valve and into the left ventricle of the heart;

locating a prosthesis as defined in claim 1 in said catheter with said valve body and said anchor device in a collapsed state, said valve body being located between said anchor device and said catheter first end;

advancing said prosthesis through said catheter until said valve body is released from said catheter first end, thereby expanding said valve body from said collapsed state;

withdrawing said catheter first end through the mitral valve into the left  
5 atrium;

withdrawing said valve body toward the left atrium, locating said valve body in the orifice of the native mitral valve;

withdrawing said catheter first end through said puncture and into the right atrium;

10 advancing said anchor device through said catheter until said anchor device is released from said catheter first end, thereby expanding said anchor device from said collapsed state;

engaging said anchor device with said inter-atrial septum about said puncture;  
and

15 withdrawing said catheter from the patient.

46. A method of treating a failed or failing mitral valve comprising the steps of:  
advancing a first end of a catheter through the venous system of a patient to be treated into the right atrium of the patient's heart;

creating a puncture in the inter-atrial septum of the heart;  
20 advancing said catheter first end through said puncture, into the left atrium, through the native mitral valve and into the left ventricle of the heart;

locating a prosthesis as defined in claim 19 in said catheter with said valve body in a collapsed state and said valve body second end located between said valve body first end and said catheter first end;

25 advancing said prosthesis through said catheter until said valve body is released from said catheter first end, thereby expanding said valve body from said collapsed state;

withdrawing said catheter first end through the mitral valve into the left atrium;

30 withdrawing said valve body toward the left atrium, wedging said valve body in the orifice of the native mitral valve; and

withdrawing said catheter from the patient.

47. A method of treating a failed or failing mitral valve comprising the steps of:  
advancing a first end of a catheter through the venous system of a patient to  
35 be treated into the right atrium of the patient's heart;

creating a puncture in the inter-atrial septum of the heart;  
advancing said catheter first end through said puncture, into the left atrium,  
through the native mitral valve and into the left ventricle of the heart;

locating a prosthesis as defined in claim 30 in said catheter with said valve  
5 body in a collapsed state and said valve body second end located between said valve body  
first end and said catheter first end;

advancing said prosthesis through said catheter until said valve body is  
released from said catheter first end, thereby expanding said valve body from said  
collapsed state;

10 withdrawing said catheter first end through the mitral valve into the left  
atrium;

withdrawing said valve body toward the left atrium, wedging said valve body  
in the orifice of the native mitral valve and engaging said prongs with cardiac structure  
surrounding an end of said orifice; and

15 withdrawing said catheter from the patient.

48. A method of treating a failed or failing mitral valve comprising the steps of:

advancing a first end of a catheter through the venous system of a patient to  
be treated into the right atrium of the patient's heart;

creating a puncture in the inter-atrial septum of the heart;

20 advancing said catheter first end through said puncture, into the left atrium,  
through the native mitral valve and into the left ventricle of the heart;

locating a prosthesis as defined in claim 40 in said catheter with said valve  
body in a collapsed state;

advancing said prosthesis through said catheter until said valve body is  
25 released from said catheter first end, thereby expanding said valve body from said  
collapsed state;

withdrawing said catheter first end through the mitral valve into the left  
atrium;

withdrawing said valve body toward the left atrium, locating said valve body  
30 in the orifice of the native mitral valve with said skirt located toward the left ventricle;  
and

withdrawing said catheter from the patient.